

K 070865

510(k) SUMMARY

510(k) NUMBER:

Pending

OCT 23 2007

SUBMITTED BY:

Applied Medical
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688
Phone: 949-713-8327
Fax: 949-713-8205
e-mail: cblake@appliedmed.com

CONTACT PERSON:

Cheryl Blake
Vice President, Regulatory Affairs and Quality Systems

DATE OF PREPARATION:

February 14, 2007

NAME OF DEVICE:

Applied Medical Expandable Vascular Sheath

TRADE NAME:

Undetermined so far

COMMON OR USUAL NAME:

Catheter Introducer

CLASSIFICATION NAME:

Catheter Introducer (870.1340)

SUMMARY STATEMENT:

Identification of the legally marketed device: The Applied Medical Expandable Vascular Sheath is substantially equivalent to Applied Medical's Expandable Vascular Sheath approved under 510(k) K963886.

Description: The Expandable Vascular Sheath is a sterile single use sheath intended to facilitate the placement and removal of vascular catheters. It is manufactured from polyester filled with Titanium Oxide and Barium. Its shape provides an optimum means of facilitating and removing catheters. The device is supplied sterile and is packaged individually in a tray sealed with a Tyvek® lid.

Intended Use: The Applied Medical Expandable Vascular Sheath is indicated for percutaneous access to the peripheral vascular system and is designed to assist in the placement and removal of catheters.

Non-clinical Testing: Bench top testing was conducted and comparisons were made to the predicated device.

Summary of Technological Characteristics: The technological characteristics are the same as or equivalent to the predicate device and introduce no new safety and effectiveness issues

when used as instructed. The materials used in the device are shown to be biocompatible according to ISO 10993-1 requirements.

Design Control / Risk Analysis/Design Verification: Design control, risk analysis and design verification activities for the subject of this 510(k) have been conducted in accordance with all applicable internal Applied Medical Procedures. The design control process employed is inclusive of the elements stipulated by 21 CFR § 820.30. The risk analysis performed identified the risks relative to the performance requirements, as specified by Applied Medical internal procedures for risk analysis. The Design Risk Assessment Profile was conducted in accordance to Applied Medical internal Standard Operating Procedures, EN 1441 standards, ISO 13485, AAMI/ISO TIR 14971, and 21 CFR § 820.30, validation and verification activities addressed the profile.

Based on the risk analysis, validation and verification activities were formally controlled and addressed by Applied Medical. The activities included the methods, tests used, and acceptance criteria applied.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2007

Underwriters Laboratories, Inc.
c/o Mr. Morten Simon Christensen
Staff Engineer & FDA Program Manager
455 E. Trimble Road
San Jose, CA 95131-1230

Re: K070865
Expandable Vascular Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: October 3, 2007
Received: October 4, 2007

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

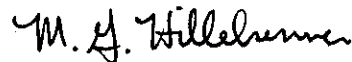
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K670865

Device Name: Expandable Vascular Sheath

Indications For Use: The Applied Medical Expandable Vascular Sheath is indicated for percutaneous access to the peripheral vascular system and is designed to assist in the placement and removal of catheters.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. G. Willhelmsen
(Division Sign-Off)
Division of Cardiovascular Devices

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